UNIVERSITY OF MIAMI

CHECKLIST: External IRB review of Human Subject Research		
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The purpose of this checklist is to provide support for IRB staff conducting Administrative Review. This checklist or equivalent is to be completed by the IRB staff, signed, dated, and retained.

IRB Number:	
Investigator:	
Reviewing IRB:	

Pre-Review

☐ A current, executed Reliance Agreement exists and, as applicable is uploaded to submission and an electronic archive.

One of the following must be checked:

☐ The human subject research is minimal risk

☐ The human subject research is greater than minimal risk and reviewing IRB is accredited by AAHRPP or equivalent body

☐ The human subject research is greater than minimal risk and reviewing IRB has an internal quality review process to ensure compliance with ethical principles, applicable law and guidance and Director or Associate Director has agreed to cede review.

☐ The University of Miami Investigator is not included on restricted list and has completed required training.

☐ The investigator and research team have completed required training.

☐ The submission includes the following items:

- Protocol
- Subject facing materials approved by the external IRB
- Investigator Brochures
- Approval letter of the external, reviewing IRB
- The reliance agreement (when necessary and/or not on file with IRB Administration)

Initial Administrative Review

If there is a local COI: (either one and two must be checked or 3 must be checked)

☐ 1. The management plan has been shared with the reviewing IRB;

☐ 2. The consent document is consistent with the requirements of the management plan.

☐ 3. N/A - No COI reported.

☐ Ancillary reviews are completed:

☐ PRMC ☐ N/A

☐ Radiation ☐ N/A

☐ IBC ☐ N/A

☐ ESCRO ☐ N/A

☐ The consent document includes the University of Miami "boilerplate" language.

☐ If subjects are compensated, include:

If you receive $600 or more during a calendar year from the University for participating in research, you may receive a 1099 for tax reporting purposes. Reimbursements for travel and other expenses are not included in this amount.

☐ If the research collects specimens include:

The University of Miami may retain, preserve, or dispose of these specimens and may use these specimens for research which may result in commercial applications. You will not receive money for donating blood, urine or tissue samples nor will you receive money from any future proceeds as a result of this research project.

☐ Compensation for Injury Language

[Non-Sponsored studies that involve greater than minimal risks:]

If you are hurt or get sick as a result of being in this study, treatment will be available in most cases. If you have insurance, your insurance company may or may not pay for these costs. If you do not have insurance, or if your insurance company refuses to pay, you will be expected to pay. Funds to compensate for pain, expenses, lost wages, and other damages caused by injury are not available. This policy does not prevent you from trying to obtain compensation through the legal system

[Sponsored studies that involve greater than minimal risks:]
If you are hurt or get sick as a result of being in this study, treatment will in most cases be available. If you experience an injury as a result of the study drug or procedures, the Sponsor will cover the cost of treatment of these injuries. Funds to compensate for pain, expenses, lost wages, and other damages caused by injury are not available. This policy does not prevent you from trying to obtain compensation through the legal system. ***[Include if applicable, otherwise delete.]*** If the sponsor pays any of your medical expenses, we may be required to give the sponsor your name, date of birth, and Medicare ID or social security number.

☐ If one or more members of the research team has a reportable financial relationship

[Study doctor] has disclosed that he/she has a personal interest related to this study.
Please ask any questions to assure yourself that this relationship has not overly influenced the conduct of this research study. If you require further information, please contact the study doctor or the University of Miami Human Subject Research Office at 305-243-3195 to ask questions or discuss concerns.

Note: The language above is an example. If the Conflict of Interest Committee requires language that is different, that required language must be substituted for the above language.

☐ Include if research information will be added to University of Miami Medical Record

If you are, or have been, a patient at a University of Miami facility, you will have a University of Miami medical record. We use an electronic medical record system known as UChart, which improves access to information important to your medical care. UChart will show that you are in a research study and a copy of this signed consent form will be included. To provide as complete a record as possible, some or all of your study-related research information may also be placed in UChart. This specifically includes investigational drugs, devices, biologics, or anything else that may, separately or together with other substances or activities, interfere with your clinical treatment or place you at greater risk of harm. Other information from the research study may be included as well. Including this information in the electronic medical record system is intended only to give information to caregivers providing treatment for you while you are on this study.

This information will be available to University of Miami doctors, nurses and other authorized staff who may not be part of the research team but who are involved in providing you medical care, or who are otherwise allowed to access your information. The confidentiality of the results and other documents in UChart will be governed by laws, such as HIPAA, that concern medical records. We suggest that you tell any non-University of Miami doctors that you are in a research study and that more information may be made available to them at your request. The research team may use your information to notify you of appointments, send you appointment reminders, or schedule additional appointments.

☐ Include if the study involves HIV, hepatitis B, or hepatitis C testing with subjects who have not already been diagnosed with those conditions:

As part of the study you will be tested for _____. Florida regulations require health care providers/laboratories to report new cases of HIV, AIDS, hepatitis infection and some STD to the county health department. If you test positive for _____, by law we have to report the personal identifiers such as name, sex, date of birth, address and phone number, and other identifying information. Information about these new infections is used to track these diseases statewide and nationwide. Other than this required reporting, your results will be kept confidential to the extent permissible under the law. The health department may contact you with resources for counseling and medical care, if you need them and want them.

☐ This study is greater than minimal risk and/or subject to FDA regulations and will undergo at least annual review.
☐ N/A - Study is minimal risk and not subject to FDA regulations, and continuing review is not required.
☐ Other

☐ The study does not waive parental permission

☐ The study does not involve an exception from the requirement for informed consent under 21 CFR 50.24

☐ The research will use a standalone HIPAA Authorization (Form B), if PHI will be collected, created or otherwise accessed. .

Comments:

☐ Acknowledgement sent to Relying Investigator

OR

☐ Deficiencies that preclude acknowledgment are conveyed to the PI for reconciliation